

What other treatments are available for me?

☾ **Drug therapy** (such as low dose birth control pill or other hormones) is frequently prescribed for excessive bleeding caused by hormonal imbalance. It is often used among women who wish to retain fertility and can be effective in decreasing bleeding without the need for surgery. Repeated, long term dosing is usually required. Minor side effects are common and may include headache, breast tenderness, and weight gain. Major complications are rare.

☾ **Dilation and curettage (D&C)** is typically the first surgical step if drug therapy fails. The top layer of the uterine lining is scraped away which may reduce bleeding, usually for only a few cycles. D&C is typically performed in an outpatient surgery setting under general anesthesia. If a polyp (small overgrowth) is removed, the problem may be corrected.

☾ **Hysteroscopic endometrial ablation** destroys and removes the uterine lining with an electro-surgical instrument or laser. The procedure may be performed under general or regional anesthesia, and involves an instrument used to view the uterus (hysteroscope), and a heat source which is inserted through the hysteroscope into the uterus. The procedure is typically performed in 30-60 minutes. Most women return to work in two to three days. This method will reduce heavy bleeding approximately 85% of the time, with light or normal reduction in some patients and elimination of bleeding in others. Risks may include accidental uterus perforation, bleeding, infection, or heart failure due to the quantity of fluids used during the procedure.

☾ **Hysterectomy** (removal of the uterus) provides a cure for excessive bleeding. It is major surgery which is usually performed under general anesthesia. Several days in the hospital and up to six weeks recovery are most common.

Talk with your doctor...understand all your options.

ThermaChoice™ Uterine Balloon Therapy

☾ A new minimally invasive choice for you and your doctor to consider in the treatment of excessive menstrual bleeding. ThermaChoice has the potential to offer:

- An alternative to hysterectomy or other major surgical procedures
- An outpatient procedure; no hospital stay
- Less need for general anesthesia
- A fast recovery, with a return to normal activity within two days for most patients
- Reduced bleeding

Talk with your doctor if you have specific questions about ThermaChoice and about your options to treat excessive bleeding.



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Excessive Menstrual Bleeding



EXHIBIT
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PENGAD-Bayonne, N.J.

You Don't Have
to Live With It Anymore!

THERMACHOICE™ Uterine Balloon Therapy™

What is ThermoChoice™ Uterine Balloon Therapy™? It is a new outpatient procedure to reduce excessive menstrual bleeding. Unlike hysterectomy, which takes out the entire uterus, the procedure just destroys the lining of the uterus by the use of heat.

What can I expect from ThermoChoice? In most cases, bleeding during your period will be reduced to moderate or light flow. Some women may experience spotting; a few may experience no bleeding at all. Clinical data has shown that up to 15% of patients may not respond to ThermoChoice therapy and may require additional treatment.

Am I a candidate for ThermoChoice? Your doctor must rule out abnormal uterine conditions like some fibroids, and your pap smear and biopsy must also be normal. This is not a treatment for uterine cancer. If you still want to have children, ThermoChoice is not an option since the uterine lining is destroyed during therapy.

How does ThermoChoice work?

First, a soft flexible balloon attached to a thin catheter (tube) is inserted into the vagina, through the cervix and placed gently into the uterus.



Then the balloon is inflated with a sterile fluid which expands to fit the size and shape of your uterus.



The fluid in the balloon is heated to 87° C (degrees) or 188° F and maintained for eight minutes while the uterine lining is treated.

When the treatment cycle is complete, all the fluid is withdrawn from the balloon and the catheter is removed. Nothing stays in your uterus.



Your uterine lining has been treated and will slough off like a period in the next 7-10 days.

A New Treatment Alternative

Can I get pregnant after treatment? This therapy should not be used if you ever want to have children — in fact, pregnancies after ablation can be dangerous for both fetus and mother. Since there is a chance pregnancy could occur, contraception or sterilization should be used after treatment. Please discuss these options with your physician.

What will I feel during the procedure? About an hour before therapy, your physician may give you medication which minimizes cramping during and after the procedure. You may also be given a mild sedative to help you relax. In most cases, you will be awake during the procedure and may experience cramping and/or discomfort. Your doctor may use a local anesthesia to numb the cervix and the uterus. Sometimes patients want to be "put to sleep" using general anesthesia after which you may experience some nausea. This is an option for you to discuss with your doctor.

What will I feel after the procedure? You may feel mild or moderate cramping like a menstrual period, and if needed, your doctor will give you a mild medication to make you more comfortable. After 1-4 hours in the recovery room, you should arrange to be driven home where you can take it easy for the rest of the day.

What can I expect after I go home? Most women can return to work and family commitments by the next day. Sexual activity can be resumed after your first check-up, usually 7-10 days. Most patients have a pinkish and watery vaginal discharge for about 2 weeks, sometimes as long as a month. In some cases, the first few periods after the procedure may continue to be heavy but will begin to improve thereafter.

Are there any post-procedure complications for which I should call my physician after I get home? You should call your physician if you develop a fever of 100.4° Fahrenheit or over, worsening pelvic pain that is not relieved by ibuprofen (e.g. Motrin or Advil) or other medication prescribed by your physician, nausea, vomiting, bowel or bladder problems, and/or a greenish vaginal discharge.

What are the risks of ThermoChoice? The procedure may pose some rare, but possible, safety risks including blood loss, heat burn of internal organs, electrical burn, perforation (hole) or rupture of the wall of the uterus, or leakage of heated fluid from the balloon into the cervix or vagina. Collection of blood or tissue in the uterus and/or fallopian tubes during the months post-procedure is also possible and may require an outpatient procedure to correct the problem.

As with any type of uterine procedure, there may also be the risk of infection, usually easily managed with oral antibiotic therapy.

Caution: This product contains natural rubber latex which may cause allergic reactions.

What you should know about excessive menstrual bleeding

I bleed so heavily every month, I can't leave home. Is this normal? Heavy bleeding is not normal, but it is common. One out of every 5 women has unusually heavy bleeding, also called menorrhagia. Women just like you have described symptoms of unmanageable bleeding, flooding, clotting and a constant need to change pads or tampons which quickly become soaked. You feel tired, worry about embarrassing accidents and are frustrated when your periods rule your life.

What causes menorrhagia? The most common cause is hormonal imbalance, especially in women 35-45, prior to menopause. Benign (non-cancerous), uterine growths, such as fibroids or polyps, infection, or chronic illness can also cause excessive bleeding.

How is excessive bleeding evaluated? In order to find the cause of bleeding and determine the right treatment for you, your doctor will take a thorough history and may perform tests which provide information about the lining of your uterus. Talk to your doctor about which tests are appropriate for your specific needs.